

Statlock® type pad that includes a removable, releasable, and replaceable clamping mechanism to clamp around a portion of catheter 10.

[0109] In embodiments in which an adhesive pad is used (e.g., Statlock® type device) to couple catheter 10 to the patient, preferably catheter 10 is removably coupled to the patient such that the adhesive pad may be changed if it becomes wet or soiled.

[0110] In FIGS. 1A-1C, fixation tab 60 is positioned on introducer 75a; in FIGS. 2A-2C, fixation tab 60 is provided on introducer 75b; in FIGS. 3A-3C, fixation tab 60 is provided on distal end 12. However, in general, fixation tab 60 may be provided at any suitable location on the sheathed indwelling catheter assembly (e.g., assembly 100a), such that the indwelling catheter (e.g., indwelling catheter 10) may be coupled to the patient during extended catheterizations. For instance, fixation tab 60 may be provided on distal end 32, on catheter 10 distal to takeoff port 17, on catheter 10 proximal to takeoff port 17, on takeoff port 17, on an introducer (e.g., introducer 75a or 75b), on a collar coupling sheath 40 to the indwelling catheter, or combinations thereof. Further, in some embodiments, no fixation tab 60 is provided. Still further, in other embodiments (e.g., FIG. 2A), more than one fixation tab 60 may be provided.

[0111] During extended use of the indwelling catheter 10, both expander 15 and fixation tab 60 may cooperate to deter withdraw of indwelling catheter 10 from the patient and to prevent excessive movement of indwelling catheter 10 relative to the patient.

[0112] In general, distal end 12 of indwelling catheter 10 may comprise any suitable geometry. Examples of suitable geometries include without limitation, flared or increased diameter distal end 12 (e.g., FIGS. 1A-1C, 4A-4G), uniform diameter distal end 12 (e.g., FIGS. 2A-2C, 3A-3C), decreasing diameter distal end 12, etc.

[0113] Further, in each of the Figures disclosed herein, distal end 12 of catheter 10 extends outside sheath 40. However, in other embodiments, part or all of non-insertable portion 30, including distal end 12, may be enclosed by sheath 40, similar to those shown in House III, which discloses catheter assemblies in which non-insertable portion 30 is partially and completely enclosed by sheath 40.

[0114] Embodiments of the sheathed indwelling catheter assembly disclosed in FIGS. 2A-2C and 3A-3C (assemblies 100b and 100c, respectively), include a removable sheath 40. Sheath 40 includes a pre-weakened tear line 48 coupled to a pull tab 49 such that sheath 40 is designed to tear along tear line 48 when pull tab 49 is pulled. Other embodiments of the sheathed indwelling catheter assembly (e.g., 100a, and d-j) may include a removable sheath 40 similar to that shown in FIGS. 1A-1C and 3A-3C. Such a removable sheath may be configured to be completely removed once tip 14 of indwelling catheter 10 is properly positioned in the patient urinary bladder or removed as tip 14 is advanced into the patient's urethra. Preferably, any removable sheath is removed in a manner to minimize opportunities for insertable portion 20 to contact a non-sterile surface.

[0115] Catheterization Kit

[0116] Referring to FIG. 5, a representative catheterization kit ("cath kit") 70 that is particularly useful for long-term patient catheterizations includes a sheathed indwelling catheter assembly 72, representative of those shown and described above as sheathed catheter assemblies 100a-j. For

example, sheathed catheter assembly 72 may include an introducer 75, catheter 10, and a sheath 40. Sheath 40 may be coupled to introducer 75, if present, and coupled to catheter 10 near the distal end 12 of catheter 10. Further, assembly 72 may include one or more vents (not shown in FIG. 5) in any suitable location including without limitation, in sheath 40, in introducer 75, in a collar (e.g., collar 43) coupling sheath 40 to catheter 10, or combinations thereof.

[0117] In addition to the sheathed catheter assembly, the kit preferably also contain one or more packaged antiseptic swabs 79 (e.g., swabs saturated with Betadine, Povidone-Iodine or other suitable antiseptic), disposable gloves 80, an adhesive pad 81 (e.g., Statlock® type adhesive pad) small urine specimen bottle (with cap) 78, and a tray 71 that holds these supplies and also serves as a urine collection container and has a capacity in the range of 700-2000 mL, preferably about 1000 mL. Preferably a fenestrated drape is also included in the kit. A gauze pad may also be included in the kit as a convenient wipe at the end of the procedure. The kit components are protected by a sanitary wrapper or cover 82. All kit components are preferably disposable.

[0118] Absent from the present kit, however, are the customary liquid antiseptic packet, cotton balls, tray for cotton balls, forceps, and packet containing lubricating jelly. In some embodiments, the fenestrated drape is also omitted from the kit without compromising sterile technique. The conventional waterproof absorbent pad is also unnecessary, as it was often included in the past primarily to provide a sterile field for placement of the sterile jelly. Preferably, the lubricant is provided within the indwelling catheter assembly. For example, a lubricating amount of sterile lubricant may be present inside the sheath lumen, or inside introducer 75. Further, in some embodiments, indwelling catheter 10 may be a lubricated hydrophilic type as is known in the art, in which case the lumen and/or the introducer 75 (e.g., an introducer) a wetting agent (e.g., water). A drawback of conventional apparatus and methods is that contact between the indwelling catheter and any non-sterile surface (e.g., nurses hands, patient's leg, etc.), as when lubricating jelly is applied, for instance, increases the risk of contamination of the indwelling catheter, which may result in a urinary tract infection. In contrast, with the present kit, if sheathed indwelling catheter assembly 72 touches anything outside the sterile field, the insertable portion of the catheter remains sterile. Another potential problem associated with conventional catheterization kits and procedures is that, if a glove touches anything outside the sterile field and then touches the catheter, the catheter may become contaminated. If a sheathed indwelling catheter assembly is employed instead, and if a glove becomes contaminated, the indwelling catheter nevertheless remains sterile inside the protective sheath. Thus, the risk of infection and patient morbidity is reduced or eliminated with use of the new catheterization kit and catheterization procedure.

[0119] Liquid antiseptic packet, cotton balls, tray for cotton balls, forceps, and packet containing lubricating jelly are not needed for carrying out a streamlined catheterization procedure with the above-described sheathed catheter assembly 72 and maintaining sterile technique.

[0120] Catheterization Procedure

[0121] Embodiments of the sheathed indwelling catheter assembly of the present disclosure (e.g., assemblies 100a-j) may be used alone or as part of catheterization kit 70. In general, the sheathed indwelling catheter assembly is employed as described above in reference to FIGS. 1A-1C, 2A-2C, and 3A-3C.